

EPA Registration No.  
3282-81  
vol. 3

## Material Sent for Data Extraction

Reg # 3282-81

Description: New CSF

☒ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated \_\_\_\_\_

☐ Notification Dated \_\_\_\_\_

☒ New CSF(s) Dated 2-6-14

☐ Other \_\_\_\_\_

☐ Decision # \_\_\_\_\_

Other Action/Comments:

Please scan clipped items – Thank you!

Reviewer: Gene Benbow

Phone: 347-0235 Division: RD - IRB

Date: 6-9-14

## Benbow, Gene

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**From:** dswain@srcconsultants.com  
**Sent:** Monday, June 09, 2014 9:57 AM  
**To:** Benbow, Gene  
**Subject:** RE: 4 CSF amendments

Good morning Gene,

Yes, each registration should have two formulations active. The one dated 1/30/12 and the new alternate dated 2/6/14.

I agree with you that the one dated 1/30/12 would now be the "Basic" and the new one dated 2/6/14 would be the only alternate now active.

The formulation for all 4 of these registrations is identical.

Does this clarify? Do you need any further revisions?

Have a great day, thanks for your help.

Best regards,

David

David M. Swain  
Scientific & Regulatory Consultants, Inc.  
Phone: 260-244-6270

**From:** Benbow, Gene [mailto:Benbow.Gene@epa.gov]  
**Sent:** Monday, June 09, 2014 9:12 AM  
**To:** dswain@srcconsultants.com  
**Subject:** 4 CSF amendments

Hi David,

I have your 4 amendments just about ready to stamp and had a question for you. The CSF records for some of these are confusing with regard to which were *accepted* and which were *superseded* (they kind of end up in a big "pile" in the folder). From what I can figure out, it appears that all 4 products have:

1 (currently marked "alternate") Basic CSF dated 1/30/12  
Alternate #1 dated 2/6/14

Obviously the Alternate #1 dated 2/6/14 is the new proposed CSFs submitted with your most recent action to switch an inert ingredient.

Let me know if this matches what you have on file for all 4 products (3282-81, 3282-65, 3282-74 and 3282-66). I have a couple of others for each which are dated much older and appear to be superseded by these.

Thanks,

Gene Benbow



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL, SAFETY  
AND POLLUTION PREVENTION

JUN - 9 2014

David Swain  
Reckitt Benckiser LLC  
339 Interpace Parkway  
Parsippany, NJ 07054

Subject: Amendment to add an additional Alternate Confidential Statement of Formula (CSF)  
dated 2/6/14  
EPA Registration No. 3282-81  
Primary Brand Name: d-CON Ready Mixed Generation II  
Submission Date: February 6, 2014

Dear Mr. Swain,

By Letter dated May 15, 2014, I rejected the above-captioned amendment request because the resultant registration would still not comply with section 3(c)(5) of FIFRA. In the recent Memorandum of Agreement (MOA) between Reckitt-Benckiser and EPA, you asked, and we agreed, to reconsider that rejection. Because the resultant registration would not increase the risk of unreasonable adverse effects on the environment when compared to the existing registration, and for the reasons behind the MOA, EPA agrees that the amendment can now be granted. The CSF referred to above, submitted in connection with registration under FIFRA, is **acceptable**. A copy will be placed in our records. **Please note that the record for this product currently contains the following CSFs:**

- Basic CSF dated 01/30/12
- Alternate #1 dated 02/06/14

Any previously dated CSFs are superseded. If you have any questions, please contact Gene Benbow at 703-347-0235 or [benbow.gene@epa.gov](mailto:benbow.gene@epa.gov).

Sincerely,

A handwritten signature in black ink, which appears to read "Meredith F. Laws", is written over the typed name.

Meredith F. Laws  
Branch Chief  
Insecticide-Rodenticide Branch  
Registration Division (7505P)

## Scientific & Regulatory Consultants, Inc.

February 6, 2014

Mr. Reuben Baris, PM-7  
Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, 4th Floor One Potomac Yard  
2777 S Crystal Drive  
Arlington, VA 22202

**SUBJECT: Amendments to add an alternate formulation for the following products:**

d-CON® Mouse Prufe II (EPA Reg. No. 3282-65)  
d-CON® Pellets Generation II (EPA Reg. No. 3282-66)  
d-CON® Bait Pellets II (EPA Reg. No. 3282-74)  
d-CON® Ready Mixed Generation II (EPA Reg. No. 3282-81)

Dear Mr. Baris:

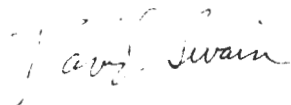
On behalf of our client, Reckitt Benckiser, LLC (Reckitt), enclosed is an action adding an alternate Confidential Statement of Formula (CSF) for the above four subject products. This is an amendment without data therefore it is not a PRIA amendment; therefore, no PRIA fee is required.

The approved CSFs for the above 4 products are all identical. They have the same formulation and the same approved suppliers for each ingredient in the formulation. Reckitt is adding an alternate formulation for each that substitutes the [REDACTED]

[REDACTED] The concentration of this inert remains the same. According to our conversation with PV Shah of the Inerts Branch, the [REDACTED] is an acceptable substitution for nonfood use. The email exchange confirming both the acceptable substitution from PV Shah as well as confirmation that the above registrations are nonfood from Jennifer Gaines are appended to this cover letter. PV Shah indicating that [REDACTED]

We look forward to a timely review of this submission. If you need any clarification or issues arise during the review of this information, please contact me immediately at 260-244-6270 or [dswain@srcconsultants.com](mailto:dswain@srcconsultants.com) for resolution.

Sincerely,



David Swain  
Agent for Reckitt Benckiser, LLC.  
Cc: Hal Ambuter

PO Box 1014  
Columbia City, IN 46725

[www.srcconsultants.com](http://www.srcconsultants.com)

P: 260.244.6270  
F: 260.244.6273

\*Inert ingredient information may be entitled to confidential treatment\*

dswain@srcconsultants.com

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**From:** Shah, Pv <Shah.Pv@epa.gov>  
**Sent:** Wednesday, January 29, 2014 6:10 PM  
**To:** dswain@srcconsultants.com  
**Cc:** InertsBranch  
**Subject:** RE: Thank you for your call - [REDACTED]

Sorry, I was in a rush and did not see second part of the question...

[REDACTED] is approved for nonfood use pesticidal formulation [REDACTED]  
[REDACTED]

P. V. Shah, Ph.D  
Chief, Inert Ingredient Assessment Branch  
Registration Division  
Office of Pesticides Programs, US EPA  
1200 Pennsylvania Ave., NW  
Washington, DC 20460 (USA)  
Phone: 703-308-1846  
Fax: 703-308-9382  
[Shah.Pv@epa.gov](mailto:Shah.Pv@epa.gov)

For FED EX and UPS Deliveries: One Potomac Yard (South Building), 2777 Crystal Drive (Room S-7751), Arlington, VA 22202

**From:** dswain@srcconsultants.com [mailto:dswain@srcconsultants.com]  
**Sent:** Wednesday, January 29, 2014 9:49 AM  
**To:** Shah, Pv  
**Cc:** InertsBranch  
**Subject:** Thank you for your call - [REDACTED]

Good morning PV,

Thank you for your call yesterday afternoon regarding my question regarding the use of the [REDACTED]  
[REDACTED] in a non-food rodenticide formulation.

Could you respond back to this email to confirm that we can use [REDACTED]  
[REDACTED] as a substitute inert ingredient [REDACTED] in a non-food use formulation?

This documentation will be helpful for our submission to revise a CSF.

Will this CAS# for [REDACTED] for non-food formulations?

Best regards,

David

David M. Swain  
Scientific & Regulatory Consultants, Inc.  
P.O. Box 1014

2/6/2014 10:55 AM

Columbia City, IN 46725

Phone: 260-244-6270

Fax: 260-244-6273

E-mail: [dswain@srcconsultants.com](mailto:dswain@srcconsultants.com)

Web site: [www.srcconsultants.com](http://www.srcconsultants.com)

This email is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information that is exempt from disclosure under law. If you have received this message in error, please inform us promptly by return email then destroy any printed copy. Thank you.

**From:** Gaines, Jennifer <gaines.jennifer@epa.gov>  
**Sent:** Monday, January 13, 2014 2:57 PM  
**To:** dswain@srcconsultants.com  
**Subject:** RE: EPA Receipt of 4 Label Amendments (3282-65, 66, 74, 81)

**Follow Up Flag:** Follow up  
**Flag Status:** Completed

Sure thing David, I'm happy to help you out. And the R301 would be the correct code for this submission. I'm teleworking today, so when I'm back in the office tomorrow I'll contact Teresa to see how we can get that changed. It might result in you submitting another form and cover letter explaining what happened; or it might be able to get changed internally without you needing to do that. But I'll find out tomorrow morning and get back to you.

As for the inert clearance, it would be cleared as a non-food inert since the product is for non-food use.

Let me know if you have anything else I can help you with.

Kind regards,  
Jennifer

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**From:** dswain@srcconsultants.com <dswain@srcconsultants.com>  
**Sent:** Monday, January 13, 2014 2:50 PM  
**To:** Gaines, Jennifer  
**Subject:** RE: EPA Receipt of 4 Label Amendments (3282-65, 66, 74, 81)

Hi Jennifer,

OK, thank you for the guidance. I think this will fit into R301, who should I contact to get the change done? I am afraid I am pretty new in "Registration Division work", having done mostly all previous work with the Antimicrobial Division. So thank you for your patience with my questions.

Also, another question while I have you. Would an inert added to a rodenticide as a food attractant need to have a food inert approval, or would it be considered a non-food inert and only need non-food approval?

Thanks again for all your help.

Best regards,

David Swain  
260-244-6270

**From:** Gaines, Jennifer [mailto:gaines.jennifer@epa.gov]  
**Sent:** Monday, January 13, 2014 9:42 AM  
**To:** dswain@srcconsultants.com  
**Subject:** RE: EPA Receipt of 4 Label Amendments (3282-65, 66, 74, 81)



## TRANSMITTAL DOCUMENT

d-CON® Mouse Prufe II (EPA Reg. No. 3282-65)  
d-CON® Pellets Generation II (EPA Reg. No. 3282-66)  
d-CON® Bait Pellets II (EPA Reg. No. 3282-74)  
d-CON® Ready Mixed Generation II (EPA Reg. No. 3282-81)

1. Name and address of submitter:

Reckitt Benckiser, LLC.  
Morris Corporate Center IV  
399 Interpace Parkway  
Parsippany, NJ 07054

2. Regulatory action in support of which this package is submitted:

Confidential Statements of Formula Amendments without data  
Non-PR1A amendment, no fee required

3. Transmittal date:

February 6, 2014

4. Vol. I Administrative materials:


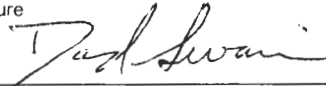
- A) Cover letter with email exchanges with PV Shah and Jennifer Gaines
- B) Applications for each product
- C) Letter of Authorization – Reckitt to SRC.
- D) Formulator's Exemption for each product
- E) Confidential statement of formula for each product
- F) MSDSs from 3 suppliers added to the CSFs for new inert. Same 3 suppliers for each CSF.

Company Official: David Swain

Company Name: Agent for Reckitt Benckiser, LLC.

David Swain, Phone (260) 244-6270

Company Contact: Email: [dswain@srcconsultants.com](mailto:dswain@srcconsultants.com)

 <b>United States</b> <b>Environmental Protection Agency</b> Washington, DC 20460		<input type="checkbox"/> Registration <input checked="" type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> Other	OPP Identifier Number
<b>Application for Pesticide - Section I</b>			
1. Company/Product Number 3282-81		2. EPA Product Manager R. Baris	
4. Company/Product (Name) d-CON® Ready Mixed Generation II		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Reckitt Benckiser LLC. 339 Interpace Parkway Parsippany, NJ 07054  <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No. _____  Product Name _____	
<b>Section - II</b>			
<input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.	
<b>Explanation:</b> Use additional page(s) if necessary. (For Section I and Section II.) Confidential Statements of Formula Amendments without data Non-PRIA amendment, no fee required			
<b>Section - III</b>			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  <b>* Certification must be submitted</b>	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt.    No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt    No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Various	
5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product		6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	
<b>Section - IV</b>			
1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name David Swain		Title Agent for Reckitt Benckiser LLC.	Telephone No. (Include Area Code) 260-244-6270
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  <b>(Stamped)</b>
2. Signature 		3. Title Agent for Reckitt Benckiser LLC.	
5. Typed Name David Swain		5. Date February 6, 2014	

# FAST-TRACK AMENDMENTS - Completeness Screening Checklist

Expert's In-Processing Signature: Don E. Galt Date: 2/18/14 PM #: (7)

EPA Reg. Number: <u>3282-81</u>		EPA Receipt Date: <u>2/7/14</u>	
1	Application Form (EPA Form 8570-1) - signed?	<input checked="" type="checkbox"/>	
2	Confidential Statement of Formula (EPA Form 8570-29) - signed?	<input checked="" type="checkbox"/>	
3	Certification with Respect to Citation of Data (EPA Form 8570-34) - signed?		<input checked="" type="checkbox"/>
4	Formulator's Exemption Statement (EPA Form 8570-27) - signed?	<input checked="" type="checkbox"/>	
5	Data Matrix (EPA Form 8570-35) [Applicable for adding me-too uses] - signed?		<input checked="" type="checkbox"/>
	a) Selective Method?		
	b) Cite-All Method?		
	c) Public copy of Matrix provided? See PR Notice 98-5		
6	Is Label included? (5 copies)		<input checked="" type="checkbox"/>
	a) Electronic Label submitted?		<input checked="" type="checkbox"/>
Comments: <u>Alt CSF</u>			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

February 11, 2014

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

MR. HAL AMBUTER  
RECKITT BENCKISER LLC  
D/B/A RECKITT BENCKISER  
399 INTERPACE PARKWAY  
PARSIPPANY, NJ 07054-0225

PRODUCT NAME: D-CON READY MIXED GENERATION II  
COMPANY NAME: RECKITT BENCKISER LLC  
OPP IDENTIFICATION NUMBER:  
EPA FILE SYMBOL: 3282-81  
EPA RECEIPT DATE: 02/07/14

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 7, at (703) 305-7356.

Sincerely,

A handwritten signature in black ink, appearing to be "S. J. ...".

Front End Processing Staff  
Information Services Branch  
Information Technology & Resources Management Division



United States  
**Environmental Protection Agency**  
 Washington, DC 20460  
**Formulator's Exemption Statement**  
 (40 CFR 152.85)

Applicant's Name and Address:

Reckitt Benckiser LLC  
 Morris Corporate Center IV  
 399 Interpace Parkway  
 Parsippany, NJ 07054

EPA File Symbol/Registration Number

3282-81

Product Name

d-CON® Ready Mixed Generation II

Date of Confidential Statement of Formula (EPA Form 8570-4)

2/6/2014

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Brodifacoum

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person, and meet the requirements of 40 CFR section 158.50(e)(2) or (3).

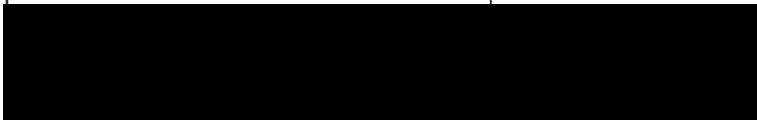
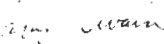
(3) Indicate by checking (A) or (B) below which paragraph applies:

- ☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- ☐ (B) The Confidential Statement of Formula (CSF) (EPA FORM 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Brodifacoum		
Signature 	Name and Title David Swain Agent, Reckitt Benckiser LLC	Date February 6, 2014



